JUN 1 6 2000

TOMTEC IMAGING SYSTEMS

K001592

March 23, 2000

Special 510(k) Summary

EchoCom
DokuCom
ImageCom

+Template Editor
+ Summary Report

Name and Address

TomTec Imaging Systems GmbH
Edisonstrasse 6
D-85716 Unterschleissheim

Name and Address Manufacturer

Individual Software GnbH
Petersburger Strasse 24-26
D-36037 Fulda, Germany

Contact Person

Florian Eisenberger
Director, Regulatory Affairs & Quality Assurance
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Common, Classification & Proprietary Names

Common Name:	Cardiac Data Analysis Program
Classification Name:	Computer Diagnostic, Programmable
Proprietary Name:	EchoCom

Predicate Device

Cone EchoCom K969665

Device Description

The Echo-Com Software is a proprietary software program for cardiac data analysis designed for installation in an IBM-compatible personal computer and use with MS Windows NT operating platform. It provides tools for ECG-triggered acquisition, display, selection, comparison, evaluation and archiving of multiple cardiac loops during various stages of a stress echo examination.
The dedicated hardware supplied with the ECHO-COM system consists of a real-time frame grabber, ECG trigger kit, control panel, hardlock, and video cable. The digitizer card interface for the frame grabber has sufficient memory

for the processing and storage of color images. This frame grabber captures all available information from the ultrasound system with which it is used during on-line operation including ECG trigger pulses and scale markers for distance measurements. The ECG trigger pulses permit time-gated cine loop recording, optimizing the system for the perfomance of stress-echo examinations.

ECHO-COM software is designed to offer exceptional flexibility during either on-line or off-line operation. Images and cine loops may be archived in a variety of commonly used formats, permitting integration into a wide range of networking systems such as InterNet and CompServe for convenient transfer of data to remote locations.

A Review Module is provided that enables users to perform measurement, calculation, and documentation of stored images and loops at the workstation. An Examination Scheme Editor permits the user to supplement the pre-programmed protocols with customized examination approaches to conform with local requirements and preferences. Data from 2-D , M-mode, and Doppler examinations can be combined as desired. Levels and scanning positions for stress-echo examinations can be freely selected. The Report and Formula Editor enables the user to add custom-designed report formats and supplementary calculation formulae to the standard menu.

A comprehensive range of cardiac ultrasound examination programs is provided including stress-echo test computations, semi-quantitative wall motion scoring, wall thickness evaluation, left ventricular volume studies, left ventricular function, color coding, M-mode functions, and Doppler functions.

The disc summation method for quantitation of left ventricular volumes by two-dimensional echocardiography, as recommended by the American Society of Echocardiography, is employed. The tolerance levels utilized in the ECHO-COM program are based directly on the range of normal values adopted by the American Society of Echocardiography. All other equations and formulae included in the ECHO-COM program are based on accepted mathematical principles or derived from the published literature.

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Intended Use

Echo-Com is dedicated to perform exercise and pharmacological stress echo examinations in conjunction with appropriate hardware and a medical ultrasound system. EchoCom is recommended for quantitative analysis of M-mode, B-mode, and Doppler ultrasound data. The system may be employed adjunctively in the performance of stress echocardiography patients with suspected coronary artery disease either online by direct connection to the video signal output port of a suitable diagnostic ultrasound system or off-line by retrieving and processing previously stored data. The system permits the use of either standard or customized examination protocols, data analysis formulae, and report formats.

Target users are physicians doing routine stress echo, i.e. the software provides maximum ease of use; an examination is completed within a minimum of time. This is achieved through an easy to follow workflow, the ability to acquire multiple cardiac loops during various phases and views without the need to store prior to completion of the examination, instant synchronized side-by-side comparison, real-time image compression, Wall Motion Scoring and LV Volume measurements.

Technological Characteristics Comparison

The new EchoCom NT is a modified version of the filed EchoCom system, which has been transferred to Windows NT operating system standards.
The graphic user interface has been Improved for faster and easier application.
Doku Com, Image Com, Template Editor and Summary Report are clinical application oriented subsets of the EchoCom Software, which makes handling easier and more efficient.

The simularities and differences between the subject and predicate devices are presented in tabular form under section H. It is concluded that the differences in technical characteristics between the two products are not signifikant in that there are no features of the subject device that raise new questions with respect to safety nor that could result in a decrease of effectiveness as compared to the predicate device.

Test Discussion

Testing was performed according to internal company procedures. Software testing and validation were done at the module and system level according to written test protocols established before testing was conducted. Test results were reviewed by designated technical professionals before software proceeded to release.

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Test Conclusions

Test results support the conclusion that actual device performance satisfies the design intent. Actual device performance as tested internally conforms to the system performance specifications.

March 23, 2000 Florian Eisenberger

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 16 2000

Mr. Florian Eisenberger
Director, Regulatory Affairs & Quality Assurance
TomTec Imaging Systems GmbH
Edisonstrasse 6
D-85716 Unterschleissheim, Germany

Re: K001592
EchoCom, ImageCom, and DokuCom
Regulatory Class: II (two)
Product Code: DQK
Dated: April 28, 2000
Received: May 23, 2000

Dear Mr. Eisenberger:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):_____

Device Name:_ TOMTEC EchoCom

Indications For Use

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(PLEASE DO NOT WRITE BELOW LINE LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K001592

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)